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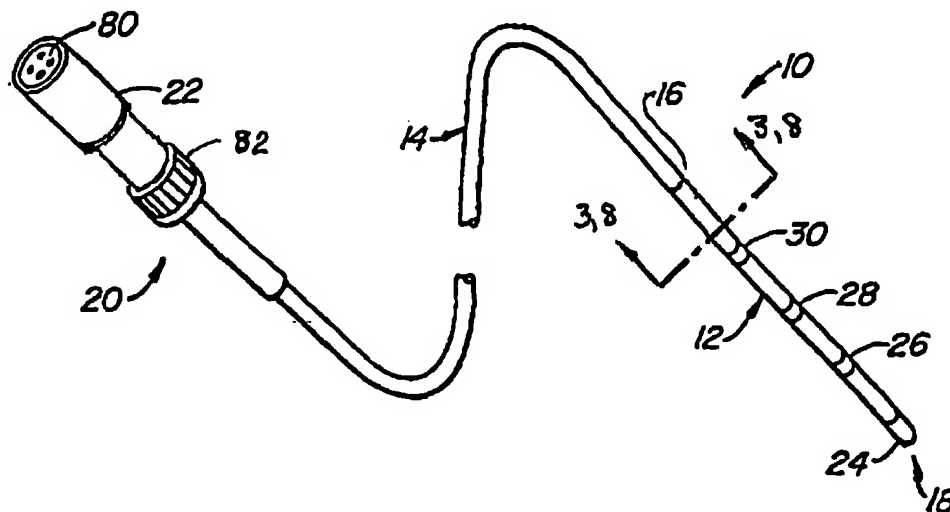
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(54) Title: MALLEABLE ELONGATED MEDICAL DEVICE



(57) Abstract: An elongated medical device insertable through an access pathway into a body vessel, organ or cavity to locate a therapeutic or diagnostic distal segment of the elongated medical device into alignment with an anatomic feature of interest having a malleable distal segment capable of being manually formed into a shape facilitating such alignment at room temperature. The elongated medical device includes a device body distal section formed of a malleable material including an elongated, malleable member disposed on or within the device body extending in the direction of the device body axis. The malleable member is formed of a Beta III titanium alloy of the type exhibiting superelastic properties when subjected to strain at a bending strain of less than a set threshold strain and capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than the set threshold at the same temperature.



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AMENDED CLAIMS

[received by the International Bureau on 4 December 2002 (04.12.2002);
original claims 1-23 amended; remaining claims unchanged (7 pages)]

1. An elongated medical device (10, 110, 210, 310) for introduction into a patient's body into conformance with an anatomical structure at a site of interest of the type characterized by an elongated device body (50, 150, 350) having device body proximal (20, 120, 220, 320) and distal ends (18, 118, 218, 318) and a device body axis, the device body further comprising a device body proximal section (14, 114, 214, 314) extending from the device body proximal end to a proximal section distal end and a device body distal section (12, 112, 212, 312) extending from the proximal section distal end to the device body distal end, wherein the device body distal section is formed of a malleable material including an elongated, malleable member (40, 42, 140, 142, 340, 342) disposed on or within the device body (50, 150, 350) extending in the direction of the device body axis, the malleable member formed of a Beta III titanium alloy of the type exhibiting superelastic properties when subjected to strain at a bending strain of less than a set threshold strain and capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than the set threshold to impart a shape enabling conformance of the distal section to the anatomical structure, the Beta III titanium alloy enabling the set shape of the malleable member to be restored to the imparted set shape following application of strain of less than the set threshold strain during introduction of the elongated medical device into a patient's body and orientation of the distal segment into conformance with the anatomical structure at the site of interest.

2. The elongated medical device of Claim 1, characterized in that the Beta III titanium alloy comprises Ti--Mb--Zr--Sn, of about 78% Ti, 11%-13% Mb, 5.4%-6.0% Zr, and 4.4%-5.0% Sn.

3. The elongated medical device of Claim 1, characterized in that the malleable member (40, 42, 140, 142, 340, 342) extends from the device

body proximal end (20, 120, 220, 320) to the device body distal end (18, 118, 218, 318).

4. The elongated medical device of Claim 1, characterized in that the malleable member (40, 42, 140, 142, 340, 342) extends through a segment of the distal section (12, 112, 212, 312).

5. An elongated catheter (110) for introduction into a patient's body into conformance with an anatomical structure at a site of interest of the type characterized by an elongated catheter (150) body having catheter body proximal and distal ends (118), a tubular side wall and a lumen (148) extending from lumen proximal and distal openings, and a catheter body axis, the catheter body further comprising a catheter body proximal section (120) joined at a proximal section distal end with a catheter body distal section (112), wherein the catheter body distal section is formed of a malleable material including an elongated, malleable member (140, 142) disposed on or within the catheter body extending in the direction of the catheter body axis, the malleable member formed of a Beta III titanium alloy of the type exhibiting superelastic properties when subjected to strain at a bending strain of less than a set threshold strain when at a predetermined temperature, and capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than the set threshold when at the predetermined temperature to impart a shape enabling conformance of the distal section to the anatomical structure, the Beta III titanium alloy enabling the set shape of the malleable member to be restored to substantially the imparted set shape following application of strain of less than the set threshold strain during introduction of the elongated medical catheter into a patient's body and orientation of the distal segment into conformance with the anatomical structure at the site of interest.

6. The catheter of Claim 5, wherein the Beta III titanium alloy characterized in that Ti--Mb--Zr--Sn, of about 78% Ti, 11%-13% Mb, 5.4%-6.0% Zr, and 4.4%-5.0% Sn.
7. The catheter of Claim 6, further characterized by a manipulator (52) coupled between the catheter body proximal end and the catheter body distal section that enables deflection of the catheter body distal section from outside the body to facilitate introduction and orientation of the distal segment into conformance with the anatomical structure.
8. The catheter of Claim 5, further characterized by a manipulator (52) coupled between the catheter body proximal end and the catheter body distal section that enables deflection of the catheter body distal section from outside the body to facilitate introduction and orientation of the distal segment into conformance with the anatomical structure.
9. The catheter of Claim 5, characterized by the malleable member (140, 142) extends from the catheter body proximal end to the catheter body distal end (118).
10. The catheter of Claim 5, characterized by the malleable member (140, 142) extends through a segment of the distal section (112).
11. The catheter of Claim 5, characterized by the conformance with the anatomical structure comprises passage of the catheter body distal end into the orifice of a branching vessel from a vessel of the vascular system.
12. The catheter of Claim 5, characterized by the conformance with the anatomical structure comprises alignment of the catheter body distal segment against an anatomical structure.

13. An elongated electro-physiology catheter (10) for introduction into a heart chamber of a patient's heart into conformance with an anatomical structure of the heart wall at a site of interest to effect mapping and/or ablation of myocardial tissue characterized by:

an elongated catheter body (50) having proximal (20) and distal (18) catheter body ends and a catheter body axis;

a handle (22) coupled to the catheter body proximal end (20);

a catheter body proximal section (14) joined at a proximal section distal end with a catheter body distal section (12);

an electrode (30, 28, 26, 24) formed in the distal section (12) for sensing cardiac signals during mapping and for delivering ablation energy during ablation;

an electrical conductor (62, 64, 66, 68) extending through the catheter body (50) from the electrode (30, 28, 26, 24) to the handle (22); and wherein:

the catheter body distal section (12) is formed of a malleable material including an elongated, malleable member (40, 42) disposed on or within the catheter body extending in the direction of the catheter body axis, the malleable member formed of a Beta III titanium alloy of the type exhibiting superelastic properties when subjected to strain at a bending strain of less than a set threshold strain and capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than the set threshold to impart a shape enabling conformance of the distal section and the electrode to the anatomical structure, the Beta III titanium alloy enabling the set shape of the malleable member to be restored to substantially the imparted set shape following application of strain of less than the set threshold strain during introduction of the elongated medical catheter into a patient's body and orientation of the distal segment into conformance with the anatomical structure.

14. The catheter of Claim 13, characterized in that the Beta III titanium alloy comprises Ti-Mb-Zr-Sn, of about 78% Ti, 11%-13% Mb, 5.4%-6.0% Zr, and 4.4%-5.0% Sn.

15. The catheter of Claim 14, further characterized by a push or pull wire (52) coupled between the handle at the catheter body proximal end and the catheter body distal section that enables deflection of the catheter body distal section from outside the body to facilitate introduction and orientation of the distal segment into conformance with the anatomical structure.

16. The catheter of Claim 13, further characterized by a push or pull wire (52) coupled between the handle at the catheter body proximal end and the catheter body distal section that enables deflection of the catheter body distal section from outside the body to facilitate introduction and orientation of the distal segment into conformance with the anatomical structure.

17. The catheter of Claim 13, characterized in that the malleable member (40, 42) extends from the handle (22) through the catheter body (50) to the catheter body distal end (18).

18. The catheter of Claim 13, characterized in that the malleable member (40, 42) extends from the catheter body distal end (18) through the distal section (12).

19. An elongated guide wire (210) for introduction into a patient's body into conformance with an anatomical structure at a site of interest of the type characterized by an elongated guide wire body having guide wire body proximal (220) and distal ends (218) and a guide wire body axis, the guide wire body further comprising a guide wire body proximal section (214) extending from the guide wire body proximal end (220) to a proximal section (214) distal end and a guide wire body distal section extending from the proximal section distal end to the guide wire body distal end (218), wherein the guide wire body distal section (212) is formed of a malleable material including an elongated, malleable member (240) disposed on or within the guide wire body extending in the direction of the guide wire body axis, the malleable member formed of a Beta III titanium alloy of the type exhibiting

superelastic properties when subjected to strain at a bending strain of less than a set threshold strain and capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than the set threshold to impart a shape enabling conformance of the distal section to the anatomical structure, the Beta III titanium alloy enabling the set shape of the malleable member to be restored to substantially the imparted set shape following application of strain of less than the set threshold strain during introduction of the elongated medical guide wire into a patient's body and orientation of the distal segment into conformance with the anatomical structure at the site of interest.

20. The elongated guide wire of Claim 19, characterized in that the Beta III titanium alloy comprises Ti-Mb-Zr-Sn, of about 78% Ti, 11%-13% Mb, 5.4%-6.0% Zr, and 4.4%-5.0% Sn.

21. The elongated guide wire of Claim 19, characterized in that the malleable member (240) extends from the guide wire body proximal end (220) to the guide wire body distal end (218).

22. The elongated guide wire of Claim 19, characterized in that the malleable member extends through a segment of the distal section (212).

23. The elongated guide wire of Claim 19, characterized in that the conformance with the anatomical structure comprises passage of the guide wire body distal end into the orifice of a branching vessel from a vessel of the vascular system.

24. A method of providing medical treatment to a living body, comprising the methods of:

providing a medical device having an elongated body, at least a portion of the elongated body including a malleable member formed of a Beta III titanium alloy which is capable of undergoing plastic flow to take a set shape when subjected to a strain of greater than a set threshold;

subjecting the malleable member to a strain greater than the set threshold when the malleable member to impart a predetermined shape to the portion of the elongated body including the malleable member;

subjecting the malleable member to a strain that is less than the set threshold to introduce the elongated body into the living body at a predetermined implant site; and

enabling the malleable member to substantially resume the set shape at the predetermined implant site.

25. The method of Claim 24, wherein the Beta III titanium alloy comprises Ti-Mb-Zr-Sn, of about 78% Ti, 11%-13% Mb, 5.4%-6.0% Zr, and 4.4%-5.0% Sn.